Vaginal Barriers and Spermicides

She had heard stories of her grandmother and her grandmother's mother. They had placed objects in their vaginas to prevent pregnancy—it was one of the very few methods they had. She was not certain how well her grandmother's barriers and chemicals worked, but she could understand how the modern-day diaphragm and spermicides could help her space her pregnancies. Her husband also liked the idea of a natural method, the type handed down through generations. Because she and her husband felt comfortable with diaphragms and spermicides, they were enthusiastic about using these methods correctly and consistently.

Since ancient times, women have placed objects in their vaginas to prevent pregnancy. Today, women have a number of options: barriers such as the diaphragm, the cervical cap, the contraceptive sponge, and the female condom; and spermicides such as those found in foams, creams, gels, and films.

OVERCOMING OBSTACLES TO USE OF BARRIER METHODS

Historically, the use of vaginal barrier methods has been limited in Africa. Few clinical providers have been available with training and experience to fit vaginal devices and provide client instruction. Many providers also appear to hold undue bias against the use of vaginal barriers. Practical obstacles, such as device and spermicide cost, and the necessity for cleaning and sterilizing devices used for fitting also may play a role. Client reluctance to use a method that requires touching the genital area is often raised as a concern. However, the success of research trials in Africa evaluating other vaginal devices (such as vaginal rings), and widespread cultural practices such as douching and use of vaginal products like drying agents in conjunction with intercourse suggest that this concern may not accurately reflect client issues.

The future role of spermicides and vaginal barrier methods will depend on research about their ability to prevent sexually transmitted infections (STIs) and their record of producing irritation. If researchers document reduced infection risk with female condoms, and they find a dose and frequency for spermicide use that does not adversely effect the risk of transmitting the human immunodeficiency virus (HIV), these methods will deserve a much wider role in Africa.

MECHANISM OF ACTION

Spermicide products have two components: a chemical that kills sperm and a base or carrier (foam, cream, jelly, film, suppository, or tablet). Spermicidal chemicals in products that are available in various parts of Africa include nonoxynol-9, octoxynol, menfegol, and benzalkonium chloride. These are detergents that kill sperm by disrupting the sperm cell membrane.

Vaginal barriers, except for the female condom, combine two contraceptive mechanisms: a physical barrier to shield the cervix and a spermicide. The presence of a cap or diaphragm device may help to hold spermicide in place against the cervix. The female condom provides a physical barrier that lines the vagina entirely and partially shields the perineum.

EFFECTIVENESS

Reported pregnancy rates for typical users range from 0% to more than 50%. Unfortunately, because clinical trials of spermicide used alone do not meet modern standards for study design and analysis, comparisons of efficacy between spermicides and other methods, or between one spermicide preparation and another, is not truly meaningful using reported rates. The pregnancy rate for typical use (26%) is based on population survey information for spermicide users in the United States; the rate for perfect use (6%) is an estimate based on rates reported and rates found for similar methods.

The diaphragm, female condom, and cervical cap provide comparable contraceptive efficacy for women who have never been pregnant (6-9% with perfect use, 20% with typical use). To For women who have been pregnant, the cap is much less effective than the diaphragm or female condom. Among these women, the typical use pregnancy rate for cervical cap use (40%) is double that for the diaphragm. The perfect use pregnancy rate for the cap among parous women is 26%.

Correct placement and timing are important for all these methods, especially for the spermicides. The spermicide applicator, tablet, suppository, or film needs to reach the cervix, which for most women is deep in the vagina. Suppositories, foaming tablets, and films require adequate time for dissolution and dispersion.

Most studies indicate that about half the women who become pregnant do not use their vaginal barrier correctly. *The other half of reported pregnancies, however, occur despite correct use.* Thus it is misleading to teach clients that improper use entirely explains method failure. Women who are young and have frequent intercourse are at a higher risk for pregnancy and are also more likely than average women to become pregnant while using a spermicide or a vaginal barrier method.

HIGH EFFICACY WITH USE OF TWO METHODS

Using two methods simultaneously, such as male condoms along with spermicide, greatly reduces the risk of pregnancy (see Table 17:1). The chance that both methods might fail at the same time is very low. This principle also applies to simultaneous use of a vaginal barrier method along with oral contraceptives or to any combination of methods except simultaneous use of male and female condoms. That combination is not recommended because male and female condoms might stick to each other and cause one or both to dislodge from their correct positions. Alternatively, a couple could use two methods simultaneously during the most fertile week in each cycle (beginning 4 days before ovulation) and a single method at other times.

Table 17:1 Perfect, simultaneous use of spermicide and condoms

Method	Contraceptive failure within 1 year (%)
Condoms used alone	3
Spermicide used alone	6
Spermicide and condom used together	0.02

Source: Kestelman and Trussell (1991)

THE CLINICIAN'S ROLE

The clinician can play an important role in helping women decide wisely about these methods and use them successfully:

- 1. Discuss any characteristics that indicate higher than average pregnancy risk, such as:³²
 - Frequent intercourse (3 or more times weekly)
 - Age less than 30 years
 - Lifestyle or home situation that makes consistent use of contraceptives difficult

- Previous contraceptive failure (any method)
- Uncertainty about the decision to avoid pregnancy
- Desire to delay (rather than prevent) next pregnancy
- 2. Talk about possible risk factors for exposure to STIs. If her risk is high, abstinence is the safest option. Encourage use of latex male condoms as an alternative or in addition to a diaphragm or cervical cap. (Female condoms should not be used simultaneously with male condoms.)
- 3. Explain the high efficacy of using two methods simultaneously (see Table 17:1).
- 4. Be sure that every woman is aware that her interval of highest fertility begins about 4 days *before* ovulation.
- 5. Be sure every woman knows about emergency contraception options for postcoital treatment (see Chapter 13 on Oral Contraceptives) and has a supply on hand.

Help the woman choose which of the available spermicide or barrier options is most likely to meet her needs. These methods differ in characteristics and in rules for their use (see Table 17:2). Such differences may make a particular option easier or more appealing for a specific woman. If the match between the method and the woman's personal needs and sexual patterns is comfortable, she may be more likely to use it consistently and correctly. For example, the diaphragm method may be cumbersome for a woman whose life involves sexual intimacy primarily on weekends. The need for extra spermicide with repeated intercourse and the 24-hour maximum wearing time may be bothersome requirements. A cap that can be left in place with no additional spermicide may be easier to use correctly. Similarly, washing and storing a cap or diaphragm and the need to have a tube of spermicide available may be obstacles for a woman who is not at her own home or does not have access to privacy for washing or storage. The contraceptive sponge is easy to use but has not had a consistent production schedule and may not always be available.

Table 17:2 Vaginal barrier methods — instructions for use

	Diaphragm	Сар
Pelvic exam required for fitting	Yes	Yes
Spermicide needed with insertion	Yes	Yes
Additional spermicide needed for repeated intercourse	Yes	No
Supplies needed to add spermicide after initial insertion	Yes	No
Container needed for storage after use	Yes	Yes
Can be used during menses	No	No
Duration of protection after insertion	6 hours	48 hours
Longest wear allowed	24 hours	48 hours

ADVANTAGES AND INDICATIONS

Spermicides and vaginal barrier methods have many advantages that make them reasonable for both temporary and long-term contraception. Spermicides and female condoms can be purchased without a visit to the clinician, and a woman can take full responsibility for their use. Spermicides can be used without any help or cooperation. These methods are a good back-up for women who are just beginning another method, do not have their other method with them, or want extra protection. Spermicides can be used as an emergency measure if a condom breaks. An application of spermicide should be quickly inserted in this instance. Spermicides can be used to provide lubrication during intercourse and can appropriately be used for lubrication with a condom. A vaginal barrier can be available for immediate protection whenever needed, no matter how long the interval between uses.

There are very few medical problems that might make use of spermicides or vaginal barriers unwise. Vaginal barriers do not cause systemic side effects and do not alter a woman's hormone patterns. For women who are not at risk for STIs, particularly HIV, and who have access to safe abortion in case of failure, the medical safety of spermicides and vaginal barrier methods is comparable to that of male condoms.

SPERMICIDES AND RISK OF STIS

Laboratory research shows that nonoxynol-9 is lethal to the organisms that cause gonorrhea, genital herpes, trichomoniasis, syphilis, and acquired immunodeficiency syndrome (AIDS). 1,11,22,36 Other spermicidal chemicals, such as octoxynol, benzalkonium chloride, and menfegol, have similar chemical properties and are also effective against these pathogens in the laboratory.³⁶ Good results in a laboratory test tube, however, do not mean that spermicide products can provide reliable protection in actual use. Even when used correctly, a vaginal product might fail to protect. For example, a spermicide might not completely spread through the vagina. Also, using spermicide causes changes in the normal bacteria of the vagina and in the normal acid balance of vaginal fluids, 27 both of which could interfere with a woman's natural defenses against infection. Research indicates that such changes actually do increase risk for urinary tract infection (see Disadvantages and Precautions, below). Spermicide chemicals also can cause vaginal irritation, which could increase the user's susceptibility to infection. Although most of the studies in this area have addressed nonoxynol-9, similar results should be expected with the other spermicidal agents currently available.³⁶

PROTECTION AGAINST COMMON STIS

Spermicides and vaginal barriers appear to have some efficacy against common bacterial STIs such as gonorrhea and chlamydia.

Many studies show that women who use these methods have a slightly reduced risk for chlamydia and gonorrhea infection. 4,29,41 Methods that combine a physical barrier, such as the diaphragm or male condom, with a spermicide appear to provide the best protection. 5 Research has also confirmed lower risks for pelvic inflammatory disease (PID) and tubal infertility for diaphragm users 7,19 as well as a lower risk for cervical cancer. 6,24,25,39 Because infection with certain types of human papillomavirus (HPV) is linked to the most common form of cervical cancer, the diaphragm may help reduce cervical cancer risk by lowering the chance of HPV infection.

The female condom, too, may help reduce the risk of STIs. When used correctly, the female condom shields both the woman and the man, and traps semen inside the condom. The female condom is made of polyurethane, which is impermeable to bacteria and viruses. Protection against the spread of trichomonas infection has been reported for the female condom, 35 but studies to document reduced risk for other STIs are not yet available.

STUDIES OF IRRITATION AND HIV OR AIDS RISK

Human studies of HIV or AIDS risk in relation to spermicide use are very limited, and results have been contradictory. The first study of HIV seroconversion rates and possible spermicide effects involved 138 sex workers in Nairobi; contraceptive sponges containing 1,000 mg of nonoxynol-9 were compared with a placebo vaginal cream that contained no spermicide. Use of spermicide sponges did not lower the risk of HIV seroconversion, and women using the spermicide sponges had more frequent genital irritation and ulceration than the placebo users.²² This result is of great concern because diseases involving ulcers may contribute to HIV susceptibility.⁴⁰ Women in this study, however, had very frequent intercourse, using 14 sponges per week on average. Thus their total exposure (dose and frequency) to spermicide was very high.

Two other small studies of HIV infection rates are more encouraging. One, which involved a group of sex workers in Cameroon, 36,43

found that use of nonoxynol-9 suppositories was associated with reduced incidence of HIV infection; the other reported a similar benefit for Zambian women with HIV-positive partners.¹²

Several researchers have confirmed that spermicide produced irritation even when women did not have intercourse and have begun to clarify the relationship between frequency of use, dose, and irritation effects. 9,11,42 In a study that provided careful examination, including colposcopy, irritation effects were documented after daily (or more frequent) use of suppositories containing 150 mg of nonoxynol. The 35 women who used spermicide suppositories every other day in this study, however, had colposcopy results indistinguishable from placebo users. 28

It may be that spermicide use is beneficial when the frequency and dose are moderate but not when the dose is high or use is very frequent. Further research is needed to provide assurance that spermicide use is not harmful and to better define an optimal dose range and frequency of use.

DISADVANTAGES AND CAUTIONS

DISADVANTAGES

Common Minor Problems

Skin irritation is the most common problem associated with spermicides and vaginal barriers that involve the use of spermicide. Some women have cramps, bladder pain, or rectal pain when wearing a diaphragm or cap, and men occasionally report penile pain during intercourse. For diaphragm users, a different size or rim type may resolve these problems.

Foul odor and vaginal discharge are likely to occur if a diaphragm or cap is inadvertently left in the vagina for more than a few days. These symptoms disappear after the device is removed. Rare cases of vaginal trauma, including abrasion and laceration, have been reported with use of the Prentif cap and the diaphragm.³

Vaginal and Urinary Tract Infections

Sexual intercourse is followed by increased vaginal colonization with *Escherichia coli*. Compared with oral contraceptive users, women who use spermicide alone or in combination with condoms have a prolonged shift in normal vaginal bacteria; among diaphragm users the shift if even more prolonged. This finding is of concern because bacterial vaginosis may be associated with increased risk for upper genital tract infection, and because it may account for the increased risk of urinary tract infection (UTI) observed among women who use the diaphragm or condoms with spermicide. The pressure a diaphragm rim places on the urethra also may contribute to the risk of developing UTI for some women.

Women who have used sponges containing nonoxynol-9 spermicide have reported an increased incidence of symptomatic candidiasis (yeast). ^{22,30} Increased vaginal colonization with Candida species has been documented after using a diaphragm with spermicide. ¹⁵ Candida is much more resistant to the microbicidal effects of nonoxynol-9 than are other normal, desirable vaginal organisms such as lactobacillus. ²¹

Toxic Shock Syndrome

Toxic shock syndrome (TSS) is an extremely rare but serious disorder caused by toxin(s) released by some strains of *Staphylococcus aureus* bacteria. Patients using vaginal barriers need to be aware of the TSS danger signs, and instructions for using the particular method should be consistent with recommended TSS precautions.³³

Systemic Effects

Serious adverse reactions have not been reported for nonoxynol-9 and octoxynol. In animal studies, large doses of nonoxynol-9 have been associated with liver toxicity and embryotoxic effects.² Three studies in humans reported possible adverse associations between spermicide exposure and birth defects, ^{17,18,31} but these studies appear to have had serious methodologic problems. Subsequent research has not found adverse fetal effects associated with spermicide use. ^{8,13,34,37} Thus, experts believe no true association exists between spermicide use and fetal defects. ^{8,13,34}

Precautions

The following conditions may make vaginal barrier methods inadvisable:

- 1. Allergy to spermicide, rubber, latex, or polyurethane or irritation symptoms related to use of the method
- 2. Abnormalities in vaginal anatomy that interfere with satisfactory fit or stable placement
- 4. History of toxic shock syndrome
- 5. For the diaphragm, repeated urinary tract infections that persist despite efforts to refit the diaphragm
- 6. For the diaphragm and cap, lack of trained personnel to fit the device and provide instruction
- 7. For the cap, full-term delivery within the past 6 weeks or recent spontaneous or induced abortion (caps should not be used during vaginal bleeding from any cause, including menstrual flow)
- 8. For the cap, known or suspected cervical or uterine malignancy, an abnormal Papanicolaou (Pap) smear result, or vaginal or cervical infection
- 9. For spermicides, caution in using these agents is indicated for a woman who is at high risk for STIs and HIV infection, or who would need to use the method very frequently (more than every other day)

PROVIDING VAGINAL BARRIER METHODS AND SPERMICIDES

SPERMICIDES

When providing spermicides in a clinical setting, reinforce instructions for proper use and remind the user about common errors that can lead to unintended pregnancy.

Foam

Foam is marketed to be used alone, but it can be used satisfactorily with a diaphragm or with a condom.

Creams and gels

Creams and gels are commonly marketed for use with a diaphragm, but they also can be used alone. One application of foam, cream, or gel provides 80 to 150 mg of spermicide, depending on the product. Spermicide concentration is 12.5% in foam and ranges from 1% to 5% in gels and creams.

Suppositories and foaming tablets

Spermicide suppositories are intended for use alone or with a condom. Suppositories provide 100 to 150 mg in a 2.3% to 8.3% concentration. Allow enough time between insertion and intercourse (10 to 15 minutes depending on the product) for the suppository to melt or foam up.

Film

Vaginal contraceptive film can be used alone or with a diaphragm or condom. Each 2" x 2" paper-thin sheet of film is 28% spermicide and contains 72 mg of nonoxynol-9. The sheet must be inserted on or near the cervix (or inside the diaphragm) at least 5 minutes before intercourse to allow time for the sheet to melt and spermicide to disperse. Placing film on the tip of the penis for insertion is not recommended as a way to use this method because the film will not have adequate time to dissolve and because the film may not reach its proper position.

VAGINAL BARRIERS

Make sure the woman can insert and remove her device correctly. Stress the importance of consistent, correct use, and explain how to

use spermicide, if it should be used with her barrier. Be sure the woman understands when to remove her barrier. A female condom should be removed immediately after intercourse; the condom should be twisted during removal to trap semen inside. A diaphragm or cervical cap, on the other hand, must be left in place for at least 6 hours after intercourse. Remind diaphragm and cap users about TSS danger signs (see Instructions for Patients in the following section).

Female condom

The female condom is a thin (0.05 mm) polyurethane sheath, 7.8 cm in diameter and 17 cm long. This soft, loose-fitting sheath contains two flexible polyurethane rings. One ring lies inside the vagina and serves as an insertion mechanism and internal anchor. The other ring forms the open edge of the device and remains outside the vagina after insertion (see Figure 17:1). The external portion of the device covers part of the perineum. Intended for one-time use, the device should not be used in conjunction with a latex male condom.

The female condom provides protection for one act of intercourse. It can be inserted any time (up to 8 hours) before intercourse and must be removed immediately after intercourse.

Diaphragm

This dome-shaped rubber cup has a flexible rim; it is inserted into the vagina before intercourse so that the back rim rests in the posterior fornix and the front rim fits snugly behind the pubic bone. The dome of the diaphragm covers the cervix. Spermicidal cream or jelly is placed inside the dome prior to insertion.

Once in position, the diaphragm provides effective contraceptive protection for 6 hours. If a longer interval has elapsed before intercourse, inserting additional, fresh spermicide with an applicator (without removing the diaphragm) is recommended. An additional applicator-full of spermicide is recommended whenever intercourse is repeated. After intercourse, the diaphragm must be left in place for at least 6 hours. Wearing it for longer than 24 hours is not recommended because of the possibility of TSS.

Figure 17:1 Reality female condom



Diaphragms are available in sizes ranging from 50 to 95 (diameter in mm) and in several styles (see Figure 17:2). The very sturdy *arcing spring rim* has firm spring strength. Most women can use this style comfortably. The arcing spring rim can often be used successfully even if a woman has a rectocele, cystocele, or lax vaginal muscle tone. The thin *flat spring rim* has a gentle spring strength that is comfortable for women with very firm vaginal muscle tone. The sturdy *coil spring rim* has a firm spring strength suitable for a woman with average muscle tone and an average pubic arch depth. A plastic diaphragm introducer (see Figure 17:3) can be used with coil or flat spring styles, but not the arcing spring rim. The *wide-seal rim* has a flexible flange approximately 1.5 cm wide attached to the inner edge of its rim. The flange is intended to hold spermicide in place inside the diaphragm and to create a better seal between the diaphragm and the vaginal wall. Wide-seal diaphragms are available with either an arcing spring rim or a coil spring rim.

Figure 17:2 Types of diaphragms

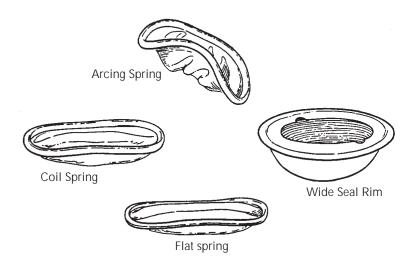
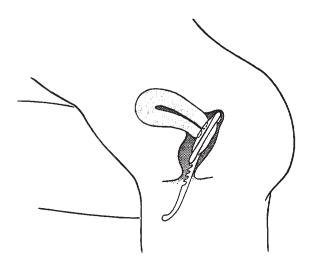


Figure 17:3 Some women prefer to use a plastic introducer for diaphragm insertion



Fitting a Diaphragm. Diaphragm manufacturers produce sets of fitting rings that are sample diaphragm rims with no dome. However, fitting rings are not adequate for patient practice. Whole diaphragms should be used for fitting so that the patient can practice insertion and removal with the sample diaphragm. To estimate the diaphragm size that will be needed:

- 1. Insert your index and middle fingers into the vagina until your middle finger reaches the posterior wall of the vagina.
- 2. Use the tip of your thumb to mark the point at which your index finger touches the pubic bone.
- 3. Extract your fingers.
- 4. Place the diaphragm rim on the tip of your middle finger. The opposite rim should lie just in front of your thumb.

Insert a sample diaphragm of the size you have selected into correct position in the patient's vagina. The device should rest snugly in the vagina, its rim in contact with the lateral walls and posterior fornix, but without tension against the vaginal walls. There should be just enough space to insert one finger tip comfortably between the inside of the pubic arch and the anterior edge of the diaphragm rim.

Choose the largest rim size that is comfortable for the patient. Try more than one rim size or type before making a final selection. Do not choose a size that is too small, because vaginal depth increases during sexual arousal (3 to 5 cm in nulliparous women), and a diaphragm that is too small may slip off the cervix. A diaphragm that is too large may create vaginal pressure, abdominal pain or cramping, vaginal ulceration, or recurrent UTIs.

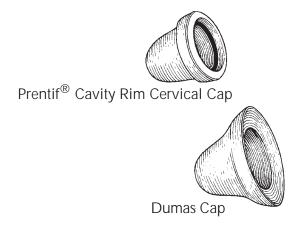
Disinfecting Diaphragm Fitting Samples. After each fitting, always wash and disinfect the sample devices:

• Wash with soap and water, and then auto clave at 121 degrees Centigrade, 15 pounds per square inch (psi) for 20 minutes unwrapped or 30 minutes wrapped; or soak in a solution of one part chlorine bleach to nine parts water for 30 minutes, rinse with water, then soak in alcohol solution (70% isopropanol or 80% ethanol) for 15 minutes after each use.²³

Cervical Cap

The cervical cap is a deep, soft rubber cup with a firm, round rim (see Figure 17:4). The Prentif cap has a groove along the inner circumference of the rim intended to improve the seal between the inner rim of the cap and the surface of the cervix. One-third of the cap's dome should be filled with spermicide before the cap is inserted; the spermicide is held in place against the cervix until the cap is removed.

Figure 17:4 Two cervical caps



The cap provides continuous protection for 48 hours, no matter how many times intercourse occurs. Additional spermicide is not necessary for repeated intercourse. Because of the possibility of developing TSS, wearing a cap for longer than 48 hours is not recommended. Some women experience odor problems with prolonged use.

Fitting a Cervical Cap. Because of variations in normal anatomy and the limited number of cap sizes available, it will not be possible to fit every patient properly. When a Prentif cap is fitted correctly, the inner diameter of the cap rim must be almost identical to, or just a few millimeters larger than, the base of the cervix. The rim forms a seal with the cervical surface. The Prentif cap rim should rest at the base of the

cervix so that the vaginal walls surround the outer side of the rim. A Dumas cap rim should rest snugly in the vaginal fornices, close to the base of the cervix. With either cap, the cervix should be completely covered. The dome of the cap should be deep enough so that it does not rest on the cervical os.

A Prentif cap that is too tight can cause cervical trauma, and one that is too loose or fails to make a secure seal over the entire circumference of the cervix will be more likely to dislodge. A woman whose uterus is acutely anteflexed, so that her cervical portio faces downward toward the back of her vagina, may find that her cap (Prentif or Dumas) dislodges. To fit a cap:

- 1. Perform a bimanual exam to determine the position and size of the uterus and cervix.
- 2. Inspect the woman's cervix to estimate the proper cap size. For a Prentif cap, the cervix must be fairly symmetrical and without extensive laceration or scarring that could interfere with uniform contact between the cap rim and cervix around its full diameter. The cervix must also be long enough to accommodate the height of the cap. A cervix that is flush or partially flush with the vaginal vault cannot be fit with a Prentif cap. In this situation, however, a Dumas cap may fit properly.
- 3. To insert the cap, fold the rim and compress the cap dome so that when it is released in place over the cervix, the unfolding dome can create suction.
- 4. Check the fit with one finger around the rim of the cap. For the Prentif cap, be sure there are no gaps between the cap rim and the cervix. Check to see how easily the cap can be dislodged.

- 5. Check for evidence of suction after the cap has been in place for a minute or two. Pinch the cap dome and tug gently. The dome should remain collapsed, and the cap should resist the tug and not slide easily out of position.
- 6. Try to rotate the cap in place. If it does not rotate at all, it is too tight; if it rotates too easily or comes off the cervix, it is too large.
- 7. To remove the cap, probe the rim with the end of your index finger; tip the cap rim to break the seal, then gently pull the cap down and out.
- 8. Try two or more cap sizes to determine the fit.

New cap users should try the cap initially while still using another method of birth control, such as condoms or oral contraceptives, to be sure that the cap remains in position after intercourse.

Disinfecting Cap Fitting Samples. After each fitting, always wash and disinfect device(s):

• Wash with soap and water, and then auto clave at 121 degrees Centigrade, 15 pounds per square inch (psi) for 20 minutes unwrapped or 30 minutes wrapped; or soak in a solution of one part chlorine bleach to nine parts water for 30 minutes, rinse with water, then soak in alcohol solution (70% isopropanol or 80% ethanol) for 15 minutes after each use.²³

Contraceptive Sponge

The sponge is round, dimpled, and made of polyurethane. It contain one gram of nonoxynol-9. The sponge protects for up to 24 hours, no matter how many times intercourse occurs. After intercourse, the sponge is left in place for at least 6 hours. After one 24-hour period of use, the sponge must be discarded.

MANAGING PROBLEMS AND FOLLOW-UP

Women using spermicides or vaginal barrier methods do not need special follow up unless they experience difficulties using their method or have symptoms of irritation, UTI, or possible TSS. After pregnancy, users should have their diaphragms and caps refitted.

Watch for symptoms that may be related to use of spermicide and barrier methods. In many cases, the woman may not suspect that her medical problem could be related to the method:

- Recurrent vaginal irritation, with no evidence of vaginal infection, may indicate allergy or sensitivity to spermicide or to latex. Changing to a different spermicide product may resolve the problem, but if it does not, the woman should avoid further exposure. Special warning is indicated for any woman who develops irritation: because susceptibility to infection with HIV may be increased, it is essential to avoid any possible exposure to STIs.
- Recurrent UTI, recurrent yeast infection, or bacterial vaginosis may be associated with using a diaphragm. In some cases, providing a smaller diaphragm size, a different rim style, or a cervical cap resolves the UTI problem. If the woman continues to have infections, she should switch to a another method of contraception that does not require use of spermicide.

A vaginal barrier user who develops signs or symptoms of TSS requires urgent, intensive evaluation and treatment. Treat the patient with antibiotics, and follow her carefully. If her symptoms are severe, she may need hospitalization. Since women who have had TSS have a greater risk than other women of getting it in the future, advise your patient to discontinue barrier methods.

No matter what other methods of contraception a woman is using, if she is at any risk because of her partner tests HIV positive or because she does not know her partner's HIV status, she should be advised to use plastic or latex condoms with every sexual act. No other contraceptive method besides abstinence provides the same degree of protection.

INSTRUCTIONS FOR BARRIER AND SPERMICIDE USERS

- 1. Use your contraceptive method every time you have intercourse. Be sure the barrier or spermicide you use is in place before beginning vaginal intercourse.
- 2. If you are using a diaphragm, sponge, or cap and have a high fever and one or more of the danger signs of toxic shock syndrome, remove the device immediately and contact your clinician.

Toxic Shock Syndrome Danger Signs

Caution

- Sudden high fever
- Vomiting, diarrhea
- Dizziness, faintness, weakness
- Sore throat, aching muscles and joints
- Rash (like a sunburn)
- 3. Wash your hands carefully with soap and water before inserting, checking, or removing your barrier or spermicide.
- 4. If you have skin irritation or vaginal irritation, stop using your contraceptive method; abstain from intercourse or use an alternative method such as male condoms. If irritation resolves in a day or two, you can try a different spermicide; otherwise, see your clinician to be sure you don't have an infection.
- 5. If you have repeated bladder or vaginal infections such as vaginal yeast, discuss this with your clinician.
- 6. If you feel unsure about the proper fit or placement of your barrier, use male condoms and see your clinician.
- 7. Do not douche right after intercourse. Douching is not recommended, but if you choose to do so, you must wait until at least 6 hours after intercourse, and after you have removed your device.

8. For extra protection against pregnancy and infection, use condoms along with your diaphragm or cap.

BEFORE INTERCOURSE

- 1. Be sure you have all the supplies you need. If you are using a diaphragm or cervical cap, you also need spermicidal cream or jelly. Check to be sure your cap or diaphragm has no holes, cracks, or tears.
- 2. Plan ahead about when to insert your method. Follow the rules for using barriers and spermicides (see below):

USING BARRIERS AND SPERMICIDE

Method	When to insert	When to remove after intercourse	Number of acts of intercourse allowed
Spermicide	Allow time for product to dissolve or spread in vagina	Douching is not recommended, but if you douche, wait at least 6 hours after intercourse	1 act with each application
Female condom	Just before or up to 8 hours ahead	Immediately after	Only 1
Diaphragm	Just before or up to 6 hours ahead	6 hours after	Unlimited with additional spermicide
Cervical cap	At least 30 minutes before	 Leave in for 6 hrs. after intercourse Remove after 48 hours of wear 	Unlimited
Contraceptive sponge	Any time before	 Leave in for 6 hrs. after intercourse Remove after 24 hours of wear 	Unlimited

INSERTION

- 1. Wash your hands carefully with soap and water.
- 2. Follow the instructions below for inserting barriers and spermicides:

Method	Instructions for insertion
Foam	Shake the foam container at least 20 times, then use the nozzle to fill the plastic applicator. Insert the applicator deeply into your vagina, close to your cervix, then push the plunger.
Jelly or cream	Fill the applicator. Insert as for foam.
Suppository	Remove the wrapping and slide the suppository into your vagina. Push it along the back wall of your vagina until it rests on or near your cervix.
Film	Place one sheet of film on a <i>very dry</i> finger tip and slide it along the back wall of your vagina until it rests on or near your cervix.
Female condom	Hold the pouch with the open end hanging down. Squeeze the inner ring closed. Insert the inner ring and the pouch into the vaginal opening and slide it the rest of the way up into the vagina. The rim on the open end will stay outside your body.
Diaphragm	Apply a finger length of spermicide inside the dome and around the rim. Squeeze the sides of the rim so that the diaphragm folds with the spermicide inside. Insert the folded diaphragm in your vagina. Push the diaphragm as far as it will go, to the back of the cervix. Tuck the front rim behind your pubic bone. Check to be sure that your cervix is covered by the soft rubber dome of the diaphragm.
Cap	Fill one-third of the dome of the cap with spermicide. Fold the rim and slide the cap into your vagina as far as it will go. Press the rim around the cervix until the cervix is completely covered. Sweep your finger around the cap rim to make sure the cervix is completely covered. The cervix should not be felt outside the cap.
Sponge	Remove the sponge from the package. Moisten it with a small handful of clean water and squeeze it once. Insert the sponge into the vagina, with the fabric loop facing toward the outside of the body. Sliding the sponge along the back wall, push the sponge to the top of the vagina so that it covers the cervix.

AFTER INTERCOURSE

- 1. Remove your female condom immediately after intercourse, before you stand up.
- 2. Leave the cap, diaphragm, or sponge in place for at least 6 hours after intercourse.
- 3. It is fine to shower or bathe with a diaphragm, cap, or sponge in place, but do not use a douche. Douching is not recommended, but if you choose to do so, you must wait until at least 6 hours after intercourse, and after you have removed your device.
- 4. Check the position of your device. If it does not seem to be in correct position after intercourse, contact your clinician about emergency birth control.

REMOVAL

Method	Instructions for removal
Female condom	Squeeze and twist the outer ring to keep semen inside the pouch. Gently pull the condom out of your vagina.
Diaphragm	Hook your finger over the front rim or behind it, then pull the diaphragm down and out. Wash the diaphragm with plain soap and water and then dry it. Hold it up to the light to check for holes, tears, or cracks.
Cervical cap	Locate the cap rim on your cervix. Press or tip the cap rim until the seal against your cervix is broken, then tilt the cap off the cervix. Hook your finger around the rim and pull it sideways out of the vagina. Wash the cap with plain soap and water, and dry it. Check the cap for holes, tears, or cracks.
Sponge	Gently pull on the fabric loop to remove the sponge from the vagina. Make certain the sponge is whole and no parts are left inside the vagina.

TAKING CARE OF YOUR SPERMICIDE SUPPLIES, DIAPHRAGM, OR CAP

- 1. Store your supplies in a convenient location that is clean, cool, and dark.
- 2. Wash devices that will be used again. Do not use perfumed soap or talcum powder.
- 3. Do not use oil-based vaginal medications or lubricants such as petroleum jelly, mineral oil, hand lotion, vegetable oil, cold cream, or cocoa butter or some common vaginal yeast creams and vaginal hormone creams. If you need extra lubrication for intercourse, try contraceptive jelly or a water-soluble lubricant specifically intended for use with condoms.

REFERENCES

- Alexander NJ, Gabelnick HL, Spieler JM (eds). Heterosexual transmission of AIDS: proceedings of the Second Contraceptive Research and Development (CONRAD) Program International Workshop, held in Norfolk, VA, Feburary 13, 1989. New York, NY:Wiley-Liss Publishers, 1990.
- 2. Anonymous. Vaginal spermicides. Med Let Drugs Ther 1986;5:13-16.
- Bernstein GS. Clark VA. Coulson AH. Frezieres R. Kilzer LF. Nakamura RM. Walsh T. Use effectiveness of cervical caps. Final Report to NICHD, Contract No. 1-HD-1-2804, 1986.
- Cates W Jr, Stone KM. Family planning, sexually transmitted diseases and con-4. traceptive choice: a literature update. Part I. Fam Plann Persp 1992;24(2):75-84.
- 5. Cates W Jr. Tubal infertility: an ounce of (more specific) prevention. JAMA 1987;257(18):2480.
- 6. Celentano DD, Klassen AC, Weisman CS, Rosenshein NB. The role of contraceptive use in cervical cancer: the Maryland cervical cancer case-control study. Am J Epidemiol 1987;126(4):592-604.
- 7. Cramer DW, Goldman MB, Schiff I, Belisle S, Albrecht B, Stadel B, Gibson M, Wilson E, Stillman R, Thompson I. The relationship of tubal infertility to barrier method and oral contraceptive use. JAMA 1987;257(18):2446-2450.
- 8. Einarson TR, Koren G, Mattice D, Schechter-Tsafriri O. Maternal spermicide use and adverse reproductive outcome: a meta-analysis. Am J Obstet Gynecol 1990;162(3):655-660.
- 9. Elias CJ, Heise L. The development of microbicides: a new method of HIV prevention for women. Working paper no.6. New York: The Population Council, 1993.
- 10. Farr G, Gabelnick H, Sturgen K, Dorflinger L. Contraceptive efficacy and acceptability of the female condom. Am J Public Health 1994;84(Number 12): 1960-1964.
- 11. Feldblum PJ, Fortney JA. Condoms, spermicides, and the transmission of human immunodeficiency virus: a review of the literature. Am J Public Health 1988;78(1):52-54.
- 12. Feldblum PJ, Hira S, Goodwin S, Kamanga J, Mukelabaie G. Efficacy of spermicide use and condom use by HIV-discordant couple in Zambia. VIII International Conference on AIDS/III STD World Congress. July 1992, abstract WeC1085.
- 13. U.S. Food and Drug Administration. Data do not support association between spermicides, birth defects. FDA Drug Bull 1986;11:21.

 14. Foxman B. Recurring urinary tract infection: incidence and risk factors. Am J
- Public Health 1990;80(3):331-333.
- 15. Hooten RM, Fennel CL, Clark AM, Stamm WE. Nonoxynol-9: differential antibacterial activity and enhancement of bacterial adherence to vaginal epithelial cells. J Infect Dis 1991;164:1216-1219.
- 16. Hooten TM, Hillier S, Johnson C, Roberts PL, Stamm WE. Escherichia coli bacteriuria and contraceptive method. JAMA 1991;265(1):64-69.
- 17. Huggins G, Vessey M, Flavel R, Yeates D, McPherson K. Vaginal spermicides and outcome of pregnancy: findings in a large cohort study. Contraception 1982;25(3):219-230.
- 18. Jick H, Walker AM, Rothman KJ, Hunter J, Holmes LB, Watkins RN, Dewart DC, Danford A, Madsen S. Vaginal spermicides and congenital disorders. JAMA 1981;245(13):1329-1332.

- 19. Kelaghan J, Rubin GL, Ory HW, Layde PM. Barrier-method contraceptives and pelvic inflammatory disease. JAMA 1982;248(2):185.
- 20. Kestelman P, Trussell J. Efficacy of the simultaneous use of condoms and spermicides. Fam Plann Perspect 1991;23(5)226-227,232.
- 21. Klebanoff SJ. Effects of the spermicidal agent nonoxynol-9 on vaginal microbial flora. J Infect Dis 1992;165(1):19-25.
- Kreiss J, Ngugi E, Holmes K, Ndinya-Achola J, Waiyaki P, Roberts PL, Ruminjo I, Sajabi R, Kimata J, Fleming TR, Anzala A, Holton D, Plummer F. Efficacy of nonoxynol 9 contraceptive sponge use in preventing heterosexual acquisition of HIV in Nairobi prostitutes. JAMA 1992;268(4):477-482.
- 23. Lettau LA, Bond WW, McDougal JS. Hepatitis and diaphragm fitting [letter to editor]. JAMA 1985;254(6):752.
- 24. Parazzini F, Negri E, LaVecchia C, Fedele L. Barrier methods of contraception and the risk of cervical neoplasia. Contraception 1989;40:519-530.
- 25. Peters RK, Thomas D, Hagan DG, Mack TM, Henderson BE. Risk factors for invasive cervical cancer among Latinas and non-Latinas in Los Angeles County. J Natl Cancer Inst 1986;77(5):1063-1077.
- 26. Prentif cavity-rim cervical cap. FDA-approved product literature, 1988.
- 27. Rekart M. The toxicity and local effects of the spermicide nonoxynol-9. J Acquir Immune Defic Syndr 1992;5(4):425-426.
- 28. Roddy RE, Cordero M, Cordero C, Fortney JA. A dosing study of nonoxynol-9 and genital irritation. Int J STD AIDS 1993;4:165-170.
- 29. Rosenberg MJ, Gollub EL. Commentary: methods women can use that may prevent sexually transmitted disease, including HIV. Am J Public Health 1992; 82(11):1473-1478.
- 30. Rosenberg MJ, Rojanapithayakorn W, Feldblum PJ, Higgins JE. Effect of contraceptive sponge on chlamydial infection, gonorrhea, and candidiasis. JAMA 1987;257(17):2308-2312.
- 31. Rothman M. Spermicide use and Down's syndrome. Am J Public Health 1982; 72(4):399-401.
- 32. Schirm AL, Trussell J, Menken J, et al. Contraceptive failure in the United States: the impact of social, economic and demographic factors. Fam Plann Perspect 1982;14(2):68-75.
- 33. Schwartz B, Gaventa S, Broome CV, Reingold AL, Hightower AW, Perlman JA, Wolf PH. Nonmenstrual toxic shock syndrome associated with barrier contraceptives: report of a case-control study. Reviews of Infections Diseases 1989; 2(1):S43-S49.
- 34. Simpson JL, Phillips OP. Spermicides, hormonal contraception and congenital malformations. Adv Contracept 1990;6(3):141-167.
- 35. Soper DE, Shoupe D, Shangold GA, Shangold MM, Gutmann J, Mercer L. Prevention of vaginal trichomoniasis by compliant use of the female condom. Sex Transm Dis 1993;20(3):137-139.
- 36. Stone AM, Hitchcock PJ. Vaginal microbicides for preventing the sexual transmission of HIV. AIDS 1994;8(Suppl 1):S285-S293.
- 37. Strobino B, Kline J, Warburton D. Spermicide use and pregnancy outcome. Am J Public Health 1988;78(3):260-263.
- 38. Trussell J, Sturgen K, Strickler J, Dominik R. Comparative contraceptive efficacy of the female condom and other barrier methods. Fam Plan Perspectives 1994:26:66-72.
- 39. Vessey MP. Contraceptive Methods: risks and benefits. Br Med J 1978;2:721-722.

- 40. Wasserheit JN. Epidemiological synergy: interrelationships between human immunodeficiency virus infection and other sexually transmitted diseases. Sex Transm Dis 1992;19(2):61-77.
- 41. Weir SS, Feldblum PJ, Zekeng L, Roddy RE. The use of nonoxynol-9 for protection against cervical gonorrhea. Am J Public Health 1994;84(Number 6): 910-914.
- 42. Zekeng L. HIV infection and barrier contraceptive use among high risk women in Cameroon. Paper presented at the International Society for Sexually Transmitted Disease Research: Banff, Canada. October, 1991.
- 43. Zekeng L, Feldblum PJ, Oliver RM, Kaptue L. Barrier contraceptive use and HIV infection among high-risk women in Cameroon. AIDS 1993;7:725-731.